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10/593,757	09/22/2006	Masaru Kimura	06662/HG	9122

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EXAMINER

SZNAIDMAN, MARCOS L

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1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/593,757

Applicant(s)

KIMURA ET AL.

Examiner

MARCOS SZNAIDMAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 3-6 and 10-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7 pages.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Comments

Applicant's response, on December 21, 2007, to Notice of non-responsive amendment, is acknowledged.

Election/Restrictions

Applicant's election of Group I (claims 1, 3-6 and 10-19) in the reply filed on November 14, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Claims 1, 3-19 are currently pending and are the subject of this office action.

Claims 7-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 14, 2007.

Claims 1, 3-6 and 10-19 are presently under examination.

Priority

The present application is a 371 of PCT/JP05/06017 filed on 03/30/2005, and claims priority to foreign application: JAPAN 2004-107084 filed on 03/31/2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 10-11, and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4, 10-11 and 14-16 refer to: "an incorporation of the generating agent into the cancer cells is accelerated". It is not clear exactly what applicant means by "accelerated" and how this is performed. The specification does not provide any explanation on how exactly this "accelerated" incorporation of the generating agent into the cancer cells is performed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiya et. al. (JAPAN 2002-047208).

Claims 1, 3, 6 and 13 recite a method of treating cancer or inducing sudden death of cancer cells by administering to a patient in need thereof a pharmaceutically effective amount of a heat and/or singlet oxygen-generating agent comprising a

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compound selected from the group consisting of an organic peroxide and a chemiluminescent compound.

For claims 1, 3, 6 and 13, Akiya teaches a method of treating cancer by administering to a patient a peroxide (especially organic peroxide) capable of generating a singlet oxygen (see abstract and paragraphs [0004] and [0005]. They also show the structures of dioxetanes (see paragraph [0009]).

Claim 17 recites the same limitations of claim 1, wherein the cancer is selected from the group consisting of: liver cancer, lung cancer, stomach cancer, large intestine cancer, skin cancer and uterine cancer.

For claim 17 Akiya et al. further teaches that the types of cancer to be treated are: liver cancer, lung cancer and pancreatic cancer (see last sentence of paragraph [0005]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 12, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiya et. al. (JAPAN 2002-047208) in view of Kimura et. al. (CAS accession # 2000:583644 corresponding to ITE Letters on Batteries, New Technologies and Medicine (2000), 1:418-421, cited by applicant).

Claims 5 and 12 recite a method of treating cancer or inducing sudden death of cancer cells by administering to a patient in need thereof a pharmaceutically effective amount of a heat and/or singlet oxygen-generating agent comprising a compound selected from the group consisting of an organic peroxide, where the peroxide is an imidazole derivative.

For claims 5 and 12, Akiya et al. teaches a method of treating cancer by administering to a patient a peroxide (especially organic peroxide) capable of

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generating a singlet oxygen (see abstract and paragraphs [0004] and [0005]. Akiya et. al. does not teach the use of a peroxide that is an imidazole derivative. However Kimura et. al. teach organic peroxides that are imidazole derivatives (for example see compound 2-(2-hydroxyphenyl)-4,5-diphenylimidazole mentioned in the abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teaching of Akiya et. al. and Kimura et. al and treat a cancer patient with any organic peroxide, including imidazole derivatives, since the chemical characteristics of these peroxides is very similar, because it is the oxygen-oxygen bond what confers to these molecules its unique characteristics, irrespective of the substituents.; thus resulting in the practice of claims 5 and 12 with a reasonable expectation of success.

Claim 18 recites a method of treating cancer or inducing sudden death of cancer cells by administering to a patient in need thereof a pharmaceutically effective amount of a heat and/or singlet oxygen-generating agent comprising a compound selected from the group consisting of an organic peroxide and a chemiluminescent compound, wherein the compound is selected from the group consisting of the structures shown in claim 18.

For claim 18, Akiya et. al. teach a method of treating cancer by administering to a patient a peroxide (especially organic peroxide) capable of generating a singlet oxygen (see abstract and paragraphs [0004] and [0005]. Akiya et. al. does not teach the use of any of the specific compounds listed in claim 18. However, Kimura et. al.

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teach the organic peroxide corresponding to the first structure of claim 18 (see compound 2-(2-hydroxyphenyl)-4,5-diphenylimidazole mentioned in the abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teaching of Akiya et. al. and Kimura et. al and treat a cancer patient with any organic peroxide (e.g. the peroxide disclosed by Kimura et. al.), since the chemical characteristics of these peroxides is very similar, because it is the oxygen-oxygen bond what confers to these molecules its unique characteristics, irrespective of the substituents.; thus resulting in the practice of claim 18 with a reasonable expectation of success.

Claim 19 recites a method of treating cancer or inducing sudden death of cancer cells by administering to a patient in need thereof a pharmaceutically effective amount of a heat and/or singlet oxygen-generating agent comprising a compound selected from the group consisting of an organic peroxide and a chemiluminescent compound, wherein the compound is selected from the group consisting of the structures shown in claim 18, and wherein the cancer is selected from the group consisting essentially of: liver cancer, lung cancer, stomach cancer, large intestine cancer, skin cancer and uterine cancer.

For claim 19, Akiya et. al. teach a method of treating cancer by administering to a patient a peroxide (especially organic peroxide) capable of generating a singlet oxygen (see abstract and paragraphs [0004] and [0005]. For claim 19, Akiya et al.

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further teach that the types of cancer to be treated are: liver cancer, lung cancer and pancreatic cancer (see last sentence of paragraph [0005]).

Akiya et. al. does not teach the use of any of the specific compounds listed in claim 18. However, Kimura et. al. teach the organic peroxide corresponding to the first structure of claim 18 (see compound 2-(2-hydroxyphenyl)-4,5-diphenylimidazole mentioned in the abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teaching of Akiya et. al. and Kimura et. al and treat a cancer (liver, lung, etc.) patient with any organic peroxide (e.g. the peroxide disclosed by Kimura et. al.), since the chemical characteristics of these peroxides is very similar, because it is the oxygen-oxygen bond what confers to these molecules its unique characteristics, irrespective of the substituents.; thus resulting in the practice of claim 19 with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS
January 28, 2008


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